IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN LABORATORIES LIMITED, MYLAN PHARMACEUTICALS INC. and MYLAN INSTITUTIONAL LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPN") (collectively "Plaintiffs" or "Janssen"), for their Complaint against Defendants Mylan Laboratories Limited ("Mylan Labs"), Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals"), and Mylan Institutional LLC ("Mylan Institutional") (collectively "Defendants" or "Mylan"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 9,439,906 (the "'906 Patent").

2. This action relates to the submission of an Abbreviated New Drug Application ("ANDA") by Mylan to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent.

THE PARTIES

3. JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. JPN is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.

5. On information and belief, Mylan Labs is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, 500034, Hyderabad, India. Upon information and belief, Mylan Labs is an agent or affiliate of Mylan Pharmaceuticals and Mylan Institutional.

6. On information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is an agent or affiliate of Mylan Labs and Mylan Institutional.

7. On information and belief, Mylan Institutional is a limited liability company organized and existing under the laws of Delaware, having a place of business at 4901 Hiawatha Drive, Rockford, Illinois 61003. Upon information and belief, Mylan Institutional is an agent or affiliate of Mylan Labs and Mylan Pharmaceuticals.

8. On information and belief, Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals are pharmaceutical companies that develop, manufacture, market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of Delaware and throughout the United States.

9. On information and belief, Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals are wholly-owned subsidiaries of Mylan Inc., a corporation organized under the laws of Pennsylvania, with a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

10. On information and belief, Mylan Inc. is a wholly-owned subsidiary of Mylan N.V., a corporation organized under the laws of the Netherlands, with a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire AL10 9UL, England.

11. On information and belief, Mylan Labs is acting on behalf of itself and on behalf of Mylan Pharmaceuticals and Mylan Institutional with respect to Mylan's ANDA No. 213124.

JURISDICTION AND VENUE

12. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and § 1400(b).

Mylan Labs

15. This Court has personal jurisdiction over Mylan Labs because, *inter alia*, Mylan Labs has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For

example, on information and belief, following approval of ANDA No. 213124, Mylan Labs will, directly or through its affiliates Mylan Pharmaceuticals and/or Mylan Institutional, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega Sustenna® brand products in the United States, including in Delaware, prior to the expiration of the '906 Patent.

16. Exercising personal jurisdiction over Mylan Labs in this district would not be unreasonable given Mylan Labs' contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

17. This Court also has personal jurisdiction over Mylan Labs because Mylan Labs has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Mylan Labs regularly and continuously transacts business within Delaware, either directly or through its affiliates—including Mylan Pharmaceuticals and Mylan Institutional—including by selling pharmaceutical products in Delaware. On information and belief, Mylan Labs derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

18. On information and belief, Mylan Labs, either directly or indirectly through Mylan Institutional or Mylan Pharmaceuticals, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

19. This Court also has personal jurisdiction over Mylan Labs because, *inter alia*, this action arises from the actions of Mylan Labs directed toward Delaware. For example, Mylan Labs' counsel sent a letter dated June 28, 2019 to JPI stating that Mylan Labs had submitted ANDA No. 213124 seeking approval to commercially manufacture, use, sell, offer for

sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent. If Mylan Labs succeeds in obtaining FDA approval, it would sell its proposed generic versions of JPI's Invega Sustenna® brand products in Delaware and other states, either directly or through its affiliates Mylan Pharmaceuticals and/or Mylan Institutional, causing injury to Plaintiffs in Delaware.

20. In the alternative, this Court has personal jurisdiction over Mylan Labs because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

Mylan Institutional

21. On information and belief, Mylan Institutional, either directly or indirectly through Mylan Labs and/or Mylan Pharmaceuticals, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

22. This Court has personal jurisdiction over Mylan Institutional because Mylan Institutional is organized under the law of Delaware, has appointed a registered agent in Delaware for receipt of service of process, has substantial, continuous and systematic contacts with Delaware, and is registered as a drug manufacturer and wholesaler in Delaware.

23. This Court has personal jurisdiction over Mylan Institutional because, *inter alia*, Mylan Institutional has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 213124, Mylan Institutional will, directly or through its affiliates Mylan Pharmaceuticals and/or Mylan Labs, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega

Sustenna® brand products in the United States, including in Delaware, prior to the expiration of the '906 Patent.

24. Exercising personal jurisdiction over Mylan Institutional in this district would not be unreasonable given Mylan Institutional's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

25. This Court also has personal jurisdiction over Mylan Institutional because Mylan Institutional has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Mylan Institutional regularly and continuously transacts business within Delaware, either directly or through its affiliates—including Mylan Pharmaceuticals and Mylan Labs—including by selling pharmaceutical products in Delaware. On information and belief, Mylan Institutional derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

26. This Court also has personal jurisdiction over Mylan Institutional because, *inter alia*, this action arises from the actions of Mylan Institutional directed toward Delaware, either directly or through Mylan Labs and/or Mylan Pharmaceuticals. For example, Mylan Labs' counsel sent a letter dated June 28, 2019 to JPI stating that Mylan Labs had submitted ANDA No. 213124 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent. If Mylan Labs succeeds in obtaining FDA approval, Mylan Institutional would sell its proposed generic versions of JPI's Invega Sustenna® brand products in Delaware and other states, either directly or through its affiliates Mylan Pharmaceuticals and/or Mylan Labs, causing injury to Plaintiffs in Delaware.

Mylan Pharmaceuticals

27. On information and belief, Mylan Pharmaceuticals, either directly or indirectly through Mylan Labs or Mylan Pharmaceuticals, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

28. On information and belief, Mylan Pharmaceuticals has substantial, continuous, and systematic contacts with Delaware, including, but not limited to, the direction of operation and management of Mylan Labs and Mylan Institutional.

29. This Court has personal jurisdiction over Mylan Pharmaceuticals because, *inter alia*, Mylan Pharmaceuticals has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 213124, Mylan Pharmaceuticals will, directly or through its affiliates Mylan Institutional or Mylan Labs, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega Sustenna® brand products in the United States, including in Delaware, prior to the expiration of the '906 Patent.

30. Exercising personal jurisdiction over Mylan Pharmaceuticals in this district would not be unreasonable given Mylan Pharmaceuticals' contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

31. This Court also has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On

information and belief, Mylan Pharmaceuticals regularly and continuously transacts business within Delaware, either directly or through its affiliates—including Mylan Institutional and Mylan Labs—including by selling pharmaceutical products in Delaware. On information and belief, Mylan Pharmaceuticals derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

32. On information and belief, Mylan Pharmaceuticals has substantial, continuous and systematic contacts with Delaware, is registered to do business in Delaware, has appointed a registered agent in Delaware for receipt of service of process, and is registered as a drug manufacturer and wholesaler in Delaware.

33. This Court also has personal jurisdiction over Mylan Pharmaceuticals because, *inter alia*, this action arises from the actions of Mylan Pharmaceuticals directed toward Delaware, either directly or through Mylan Labs and/or Mylan Institutional. For example, Mylan Labs' counsel sent a letter dated June 28, 2019 to JPI stating that Mylan Labs had submitted ANDA No. 213124 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent. If Mylan Labs succeeds in obtaining FDA approval, Mylan Pharmaceuticals would sell its proposed generic versions of JPI's Invega Sustenna® brand products in Delaware and other states, either directly or through its affiliates Mylan Labs and/or Mylan Institutional, causing injury to Plaintiffs in Delaware. Furthermore, upon information and belief, Mylan Pharmaceuticals is Mylan Labs' authorized agent with respect to ANDA No. 213124.

Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals

34. On information and belief, Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals, along with other subsidiaries of Mylan N.V., hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in Delaware and throughout the United States.

35. On information and belief, at least 35 subsidiaries of Mylan N.V.—including Mylan Institutional—are organized or incorporated under the laws of Delaware.

36. On information and belief, Mylan Labs, Mylan Institutional and Mylan Pharmaceuticals are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 213124.

37. On information and belief, Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 213124.

38. On information and belief, Mylan Pharmaceuticals and Mylan Institutional, together with their affiliate and/or agent Mylan Labs, filed the Mylan ANDA with the FDA that is at issue in this patent infringement suit.

39. On information and belief, Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals, alone and/or together with each other as affiliates and/or agents, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission

of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs in Delaware.

THE PATENT-IN-SUIT

40. On September 13, 2016, the '906 Patent, titled "Dosing Regimen Associated with Long Acting Injectable Paliperidone Esters" was duly and legally issued to JPN as assignee. A copy of the '906 Patent is attached as Exhibit A.

41. JPI holds approved NDA No. 022264 for paliperidone palmitate extended release injectable suspension, which is prescribed and sold under the trademark Invega Sustenna®.

42. Pursuant to 21 U.S.C. § 355(b)(1), the '906 Patent is listed in the United States FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering JPI's Invega Sustenna® brand paliperidone palmitate extended release suspension products.

43. Invega Sustenna® is indicated for treatment of schizophrenia in adults and treatment of schizoaffective disorder in adults as a monotherapy and as an adjunct to mood stabilizers or antidepressants.

CLAIM FOR RELIEF:
INFRINGEMENT OF THE '906 PATENT BY MYLAN

44. Plaintiffs re-allege paragraphs 1-43 as if fully set forth herein.

45. An actual controversy exists between the parties as to whether Mylan's proposed sale of its generic paliperidone palmitate extended-release injectable suspension products infringes at least one claim, including claim 1, of the '906 Patent.

46. By letter dated June 28, 2019 ("Mylan Notice Letter"), Mylan Labs notified Plaintiffs that it had submitted ANDA No. 213124 to the FDA under § 505(j) of the

Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter stated that ANDA No. 213124 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of generic paliperidone palmitate extended-release injectable suspension products prior to the expiration of certain of JPN's Orange Book listed patents. ANDA No. 213124 specifically seeks FDA approval to market generic versions of JPI's Invega Sustenna® brand paliperidone palmitate extended-release injectable suspension products in 39 mg, 78 mg, 117 mg, 156 mg, and 234 mg doses prior to the expiration of the '906 Patent.

47. ANDA No. 213124 includes a Paragraph IV Certification that the claims of the '906 Patent are invalid, unenforceable, and/or not infringed.

48. The Mylan Notice Letter was sent to Plaintiffs via overnight mail on July 1, 2019 and received by Plaintiffs on July 2, 2019. Plaintiffs commenced this action within 45 days of the date of receipt of Mylan's Notice Letter.

49. The Mylan Notice Letter purports to include a Notice of Certification for ANDA No. 213124 under 37 C.F.R. § 314.95(c)(6) as to the '906 Patent. The Mylan Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '906 Patent.

50. Mylan has actual knowledge of the '906 Patent, as shown by the Mylan Notice Letter.

51. On information and belief, Mylan's generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '906 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

52. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim, including at least claim 1, of the '906 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 213124 seeking approval to manufacture, use, import, offer to sell or sell Mylan's generic products before the expiration date of the '906 Patent. Upon information and belief, the products described in ANDA No. 213124 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '906 Patent under 35 U.S.C. § 271(e)(2)(A).

53. On information and belief, physicians and/or patients will directly infringe at least one claim, including at least claim 1, of the '906 Patent by use of Mylan's generic products upon approval.

54. On information and belief, upon approval, Mylan will take active steps to encourage the use of Mylan's generic products by physicians and/or patients with the knowledge and intent that Mylan's generic products will be used by physicians and/or patients in a manner that infringes at least one claim, including at least claim 1, of the '906 Patent for the pecuniary benefit of Mylan. Pursuant to 21 C.F.R. § 314.94, Mylan is required to copy the FDA-approved Invega Sustenna® labeling. Mylan specifically intends its generic paliperidone palmitate products to be used according to its proposed labeling in a manner that infringes at least one claim, including at least claim 1, of the '906 Patent. Upon information and belief, Mylan will thus induce the infringement of at least one claim, including at least claim 1 of the '906 Patent.

55. On information and belief, if the FDA approves ANDA No. 213124, Mylan will sell or offer to sell its generic products specifically labeled for use in practicing at least one claim, including at least claim 1 of the '906 Patent, wherein Mylan's generic products are a material part of the claimed invention, wherein Mylan knows that physicians will prescribe

and patients will use Mylan's generic products in accordance with the instructions and/or label provided by Mylan in practicing at least one claim, including at least claim 1 of the '906 Patent, and wherein Mylan's generic paliperidone palmitate extended-release injectable suspension products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Mylan's generic paliperidone palmitate extended-release injectable suspension products are specifically designed for use in a manner that infringes at least one claim, including at least claim 1, of the '906 Patent. On information and belief, Mylan will thus contribute to the infringement of at least one claim, including at least claim 1 of the '906 Patent.

56. On information and belief, the actions described in this Complaint relating to Mylan's ANDA No. 213124 were done by and for the benefit of Mylan.

57. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

58. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that the Court grant the following relief:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Mylan has infringed at least one claim of the '906 Patent through Mylan's submission of ANDA No. 213124 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Mylan's proposed generic versions of JPI's Invega Sustenna® brand product identified in this Complaint in the United States before the expiration of the '906 Patent;

B. Enter judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Mylan's commercial manufacture use, offer for sale, or sale within the United States, or importation into the United States of Mylan's proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint, prior to the expiration of the '906 Patent, constitutes infringement of one or more claims of the '906 Patent under 35 U.S.C. § 271(a), (b), or (c);

C. Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 213124 be a date that is not earlier than the expiration date of the '906 Patent, or such later date as the Court may determine;

D. Order that Mylan, its affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Mylan, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling Mylan's proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint, and any other product that infringes or contributes to the infringement of the '906 Patent, prior to the expiration of the '906 Patent, or such later date as the Court may determine;

E. If Mylan engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint prior to the expiration of the '906 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorneys' fees; and

G. Award such further and other relief that the Court deems proper and just.

MORRIS, NICHOLS, ARSHT &TUNNELL LLP

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